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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,457	06/12/2006	Stanley E. Charm	0656-027US3	2110

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Charm Sciences, Inc.
Richard J. Long
659 Andover Street
Lawrence, MA 01843

EXAMINER	
MCKANE, ELIZABETH L	

ART UNIT	PAPER NUMBER
1797	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,457	CHARM ET AL.	
	Examiner	Art Unit	
	ELIZABETH L. MCKANE	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 June 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,8,11,15-22,33,34,42-46,51,52,54,56,58,61,62,64-68 and 75* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,8,11,15-22,33,34,42-46,51,52,54,56,58,61,62,64-68 and 75* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claim 1 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al. (US 5,389,335).

Charm et al. teaches a method of inactivating an agent in a heat-sensitive material. The method of Charm et al. includes the steps of heating the material at a rate of greater than 50 °C per second to a temperature of at least 60 °C (col.3, lines 60-63), cooling the material at a rate of greater than 100 °C per second (col.8, lines 28-30), and circulating the material at a flow rate of 100 L/hr (col.7, lines 6-7). Although Charm et al. does not teach a flow rate of *greater than* 100 L/hr, the disclosure in Charm et al. of a flow rate of 100 L/hr renders obvious flow rates such as 100.1 L/hr, which would be greater than 100 L/hr.

4. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al. as applied to claim 1 above, and further in view of Nikdel et al. (US 5,667,828).

Although Charm et al. teaches that the heating is achieved through exposure to a microwave generator **14**, the frequency of the microwave energy is not disclosed. Nikdel et al., however, teaches that it was known in the art at the time of the invention to employ microwave generators operating at 2450 MHz for heat pasteurization of heat-sensitive products. See col.3, lines 36-39. It would have been obvious to one of ordinary skill in the art to use the microwave generators of Nikdel et al. in the invention of Charm et al., as Nikdel et al. evidences their successful use in the heat treatment of sensitive fluids.

5. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al. as applied to claim 1 above, and further in view of Nikdel et al. and Zietlow et al. (US 5,869,817).

Although Charm et al. teaches that the heating is achieved through exposure to a microwave generator **14**, the frequency and power capacity of the microwave energy is not disclosed. Nikdel et al., however, teaches that it was known in the art at the time of the invention to employ microwave generators operating at 2450 MHz for heat pasteurization of heat-sensitive products. See col.3, lines 36-39. It would have been obvious to one of ordinary skill in the art to use the microwave generators of Nikdel et al. in the invention of Charm et al., as Nikdel et al. evidences their successful use in the heat treatment of sensitive fluids.

Zietlow et al. teaches that the "largest currently commercially available 2450 MHz magnetron is about 15 kW" (col.9, lines 61-63). Thus, for large throughput operations, it would have been obvious to employ a high power capacity microwave generator as disclosed by Zietlow et al., where the results are not unexpected.

6. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al. as applied to claim 1 above, and further in view of Joseph et al. (US 4,788,075).

Charm et al. discloses that the step of cooling comprises passing the heated liquid material through a single heat exchanger. Charm et al. is silent with respect to use of both a tube in shell heat exchanger and a plate heat exchanger. Joseph et al. teaches method of sterilizing a heat sensitive material wherein the after heating, the material is cooled in two heat exchangers. Each heat exchanger may be either a plate or tube heat exchanger. See claim 1, steps (e) and (f). One of ordinary skill in the art would have found it obvious to use the series of heat exchangers of Joseph et al. for the single heat exchanger of Charm et al., as the two heat exchangers of Joseph et al. are more efficient at cooling than the single heat exchanger of Charm et al..

7. Claims 5, 8, 11, 15-17, 33, 34, 42-46, 51, 52, 54, 56, 66-68, and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al. in view of Nikdel et al. and Zietlow et al..

Charm et al. teaches a method of inactivating an agent in a heat-sensitive material. The agent may be a virus (col.4, lines 29-31) or microorganism (col.1, lines 51-55) and the heat-sensitive material contains a protein (col.1, line 50). The method of Charm et al. includes the steps of heating the material at a rate of greater than 50 °C

per second to a temperature of at least 60 °C (col.3, lines 60-63), cooling the material at a rate of greater than 100 °C per second (col.8, lines 28-30) in a tube in shell heat exchanger **58**, and circulating the material at a flow rate of 100 L/hr (col.7, lines 6-7). The tubing **56** through which the material is circulated has a diameter of 1/16 to ½ inch (col.5, lines 51-53). A control module **12** controls the process and is remote from the power supply **14** and the utility module **58**, where the heat sensitive material contacts a source of heating fluid and a source of cooling fluid. See Figures 1 and 2. As further shown in Figure s 1 and 2, waveguide **16** is secured to a removable plate **48**. The protein is disclosed to have a recovery of 85% (col.8, lines 32-33). Although Charm et al. does not teach a flow rate of *greater than* 100 L/hr, the disclosure in Charm et al. of a flow rate of 100 L/hr renders obvious flow rates such as 100.1 L/hr, which would be greater than 100 L/hr.

Although Charm et al. teaches that the heating is achieved through exposure to microwave energy from a waveguide **16** and microwave generator **14**, the frequency and power capacity of the microwave energy is not disclosed. Nikdel et al., however, teaches that it was known in the art at the time of the invention to employ microwave generators operating at 2450 MHz for heat pasteurization of heat-sensitive products. See col.3, lines 36-39. It would have been obvious to one of ordinary skill in the art to use the microwave generators of Nikdel et al. in the invention of Charm et al., as Nikdel et al. evidences their successful use in the heat treatment of sensitive fluids.

Zietlow et al. teaches that the "largest currently commercially available 2450 MHz magnetron is about 15 kW" (col.9, lines 61-63). Thus, for large throughput operations, it

would have been obvious to employ a high power capacity microwave generator as disclosed by Zietlow et al., where the results are not unexpected.

With respect to claims 44-46 specifically, Charm et al. teaches that the protein is disclosed to have a recovery of 85% (col.8, lines 32-33). However, the examiner submits that the method of the combination would have achieved the recovery levels claimed by the instant invention.

8. Claims 21 and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al., Nikdel et al., and Zietlow et al. as applied to claim 17 above, and further in view of Demers (US 1,826,750).

Although Charm et al. discloses the use of a tube and shell heat exchanger, a primary and secondary coolant chamber within a jacket of the heat exchanger is not disclosed. Demers, however, teaches that the use of a primary and secondary coolant chamber within the jacket of a heat exchanger is very old and well-known technology. Demers, in fact, discloses that the secondary coolant chamber (annular chamber formed between **14** and **21**) receives coolant from the primary chamber (annular chamber formed between **16** and **21**). As the results of using the heat exchanger would have only been expected and as the technology is well-known in the art, it would have been obvious to use the tube and shell heat exchanger of Demers in the invention of Charm et al..

9. Claims 18-20, 58, 61, 64, and 65 are rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al., Nikdel et al., and Zietlow et al. as applied to claims 5 and 51 above, and further in view of Joseph et al..

Charm et al. discloses that the step of cooling comprises passing the heated liquid material through a single heat exchanger. Charm et al. is silent with respect to use of both a tube in shell heat exchanger and a plate heat exchanger. Joseph et al. teaches method of sterilizing a heat sensitive material wherein the after heating, the material is cooled in two heat exchangers. Each heat exchanger may be either a plate or tube heat exchanger. See claim 1, steps (e) and (f). One of ordinary skill in the art would have found it obvious to use the series of heat exchangers of Joseph et al. for the single heat exchanger of Charm et al., as the two heat exchangers of Joseph et al. are more efficient at cooling than the single heat exchanger of Charm et al..

10. Claim 62 is rejected under 35 U.S.C. 103(a) as being unpatentable over Charm et al., Nikdel et al., Zietlow et al., and Joseph et al. as applied to claim 58 above, and further in view of Demers.

Although Charm et al. discloses the use of a tube and shell heat exchanger, a primary and secondary coolant chamber within a jacket of the heat exchanger is not disclosed. Demers, however, teaches that the use of a primary and secondary coolant chamber within the jacket of a heat exchanger is very old and well-known technology. Demers, in fact, discloses that the secondary coolant chamber (annular chamber formed between **14** and **21**) receives coolant from the primary chamber (annular chamber formed between **16** and **21**). As the results of using the heat exchanger would

have only been expected and as the technology is well-known in the art, it would have been obvious to use the tube and shell heat exchanger of Demers in the invention of Charm et al..

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH L. MCKANE whose telephone number is (571)272-1275. The examiner can normally be reached on Mon-Fri; 5:30 a.m. - 2:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a

USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth L McKane/
Primary Examiner, Art Unit 1797

elm
16 March 2009